REMARKS

This Amendment is filed in response to the Office Action dated August 28, 2002. A petition for a two-month extension of time is enclosed. Claims 1-7 and 9-20 are pending in this application. Claims 8 and 9 are cancelled, without prejudice.

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) as the stylet and shaping mechanism are not shown in the figures. Applicants have cancelled claims 8 and 9 thereby rendering the objection moot. With regard to the blood flow device, claim 20 has been amended to replace "blood flow device" with "arterial return cannula", a term that has support throughout the specification. claims 10 and 16, the same have been amended in accordance with the Examiner's assumptions. The Examiner objected to the drawings as failing to comply with 37 C.F.R. § 1.84(p)(5) because reference numeral 116 is included in drawing 8, but is not described in the specification. Applicants have amended the specification at page 19, last paragraph to include a reference to "opening 116".

Further, Applicants have amended Figure 4 to include reference numerals 62a and 70 to correct an error located by the Examiner. A copy of the changes is indicated in red ink on an enclosed copy of Figure 4. Applicants will submit a formal drawing to make the proposed changes to Figure 4.

The Examiner also objected to the specification due to a list of informalities found on page 3 of the Official Action. Applicant has made corrections to the specification to correct these errors.

In view of the above, Applicants respectfully request that the Examiner withdraw the objections to the drawings and the specification.

The Examiner rejects claim 20 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art what was being claimed. As discussed above, Applicants have amended claim 20 to replace "blood flow device" with "arterial return cannula", a term that has support throughout the specification. For example, Figures 12-14 and 18 all depict arterial return cannulas that are positionable in an artery downstream of the occlusion member for maintaining circulation of oxygenated blood in the patient's arterial system.

Accordingly, it is respectfully requested that the rejection of claim 20 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner rejected claims 1-3, 5-8, 11, 12, 14-17, 19 and 20 under 35 U.S.C. § 102(b) as being anticipated by Sweezer (U.S. Patent No. 5,478,309). Applicants respectfully traverse this rejection. Applicants have amended claims 1, 19 and 20 to more clearly claim the subject invention.

Applicants submit that Sweezer does not teach or disclose the cardioplegia catheter of claims 1-3, 5-8, 11, 12, 14-17, 19 and 20. The Examiner states that Sweezer discloses a cardioplegia catheter "comprising a shaft, having a distal and proximal end, an opening (36 or 11 or 14 etc.) near the distal end, an inner lumen fluidly connecting to the port at the proximal end and an occlusion member (6 or 8 or 27)." Sweezer, however, discloses a different approach than that disclosed in the subject application. Rather than entering the heart through the left atrium and passing through the mitral valve and aortic valve into the aorta, the catheter in Sweezer approaches the aorta from a different direction: from the subclavian artery (Fig 3) or the femoral artery (Fig 21) or the brachiocephalic artery (Fig 40) or through a puncture in the aorta (Figs 39 and 41). In each case, the catheter has an opening for delivering cardioplegia at its distal end, at a location ***distal*** to the occlusion member. In this way, the opening is positioned to deliver cardioplegia to the coronary arteries when the occlusion member is positioned between the brachiocephalic artery and the coronary ostia.

In contrast, each of claims 1, 19 and 20 claim that the cardioplegia catheter includes an opening near the distal end and an occlusion member mounted on the shaft ***distally*** of the opening. Therefore, the opening of the cardioplegia catheter is ***proximal*** the occlusion member rather than distal to the occlusion member as shown in Sweezer.

The Examiner further states that "with respect to placement of the device in the areas of the heart, Sweezer is capable of being configured for those locations." Applicants disagree with this statement. Sweezer does not teach or disclose a catheter configured such that a distal portion of the shaft extends into the ascending aorta when a proximal portion of the shaft extends into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof.

For the above reasons, Applicants respectfully request that the Examiner withdraw the rejection.

The Examiner rejected claims 1, 4-6, 11-13, and 17-19 under 35 U.S.C. § 102(e) as being anticipated by Boyd (U.S. Patent No. 5,558,644). Applicants respectfully traverse this rejection. Applicants submit that Boyd does not teach or disclose the cardioplegia catheter of claims 1, 4-6, 11-13, and 17-19. Similar to the deficiencies in Sweezer, the cardioplegia catheter of Boyd approaches the heart from a different direction and further has a different purpose. The catheter of Boyd is introduced in the right internal jugular vein and advanced to the right atrium and into the coronary sinus. See col 8, lines 13-20 and Figure 4. As with Sweezer the opening in Boyd is located distal the occlusion member to deliver cardioplegia at the distal end of the catheter. Further, the catheter is not configured such that a distal portion of the shaft extends into the ascending aorta when a proximal portion of the shaft extends into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof. Further, the occlusion member is not configured to occlude the ascending aorta between the brachiocephalic artery and the coronary ostia. As a result, Applicants respectfully request that the Examiner withdraw the rejection.

The Examiner rejects claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Sweezer in view of Brennan (U.S. Patent No. 5,439,006). Applicants have cancelled claim 9 thereby mooting the rejection.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "Version with markings to show changes made".

Once the Examiner has had time to review this Amendment, the Examiner is requested to telephone the Applicants' agent at a convenient time to discuss the prior art. Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: _____

Brian S. Tomko
Reg. No. 41,349

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1239
(732) 524-5575 (fax)
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

CROSS-REFERENCE TO RELATED APPLICATION

This application is continuation of copending U.S. patent application no. 5 08/839,189, filed April 23, 1997, now issued as U.S. Patent No. 6,090,086, the complete disclosure of which is incorporated herein by reference.

Please amend Page 11, line 1 through Page 12, line 11as follows:

First lumen 30 and first opening 34 are dimensioned to allow cardioplegic fluid to be delivered at sufficient rates to induce cardioplegic arrest effectively and rapidly. Usually, first lumen 30 will be configured for delivery of a cardioplegic fluid containing blood, which has been shown to more effectively protect the myocardium while the heart is arrested. In such cases, it is important that first lumen 30 allow the cardioplegic fluid to be delivered at sufficient rates to rapidly flow from the aortic root into the coronaries, perfuse the myocardium, and arrest the heart, without requiring the fluid to be delivered at excessive pressures which could damage the blood cells contained in the fluid. Preferably, first lumen 30 will permit delivery of cardioplegic fluid at rates of at least about 150 ml/min and at pressures no more than about 350 mmHg. Thus, first lumen 30 usually has a transverse cross-sectional area of about 2.0-3.0 mm^2, and preferably about 2.4-2.8mm^2 between first port 32 and first opening 34.

Please amend Page 14, line 25 through Page 15, line 11, as follows:

In an additional aspect of the invention, illustrated in Figure 3B, a pulmonary artery catheter 69 and a coronary sinus catheter 71 are utilized in conjunction with cardioplegia catheter 20. These catheters may be introduced transluminally into the heart from a peripheral vein such as internal jugular vein IV. Pulmonary artery catheter 69 is advanced from right atrium RA through the tricuspid valve TV, right ventricle RV and pulmonary valve PV into the pulmonary artery P A. The catheter is connected at its proximal end to a pump or other

fluid aspiration device. Any blood or fluids not removed by venous cannula 51 that reach the pulmonary artery may be removed through pulmonary artery catheter PV, thereby Ii keeping the heart adequately vented. Blood removed through pulmonary artery catheter 69 may be returned to blood filter/recovery module 65 for treatment and return to the body via cardiopulmonary bypass system 55. Other aspects of pulmonary artery catheters suitable for use in conjunction with the present invention are described in copending application No. 08/415,238, filed March 30, 1995, now abandoned, which is incorporated herein by reference.

Please amend Page 16, line 1 through line 16 as follows:

A preferred technique of positioning cardioplegia catheter 20 in the ascending aorta is shown in Figures 4-6. In this technique, a purse-string suture 60 is placed in the left atrial wall W around the intended site of catheter introduction, as shown in Figure 4. Suture 60 may be placed using well-known techniques, and is preferably placed using thoracoscopic instruments introduced through small incisions, trocar sleeves or other intercostal access ports not requiring a gross thoracotomy. The left atrium may be accessed via access ports in the 3rd, 4th or 5th intercostal spaces on the right lateral or right anterior side of the chest. If desired, the heart may be repositioned within the chest to improve access using thoracoscopic retraction instruments introduced through access ports between the ribs. Once purse-string suture 60 has been placed in wall W, a small incision or puncture P is formed in wall W so as to be encircled by suture 60, and a flow-directed catheter 64, shown in Figure 5, is inserted through puncture P. The free ends 62 of suture 60 may then be tensioned so as to form a seal between wall W and the outer wall of flow-directed catheter 64. Preferably, a suture tensioner 66 is used to maintain tension on suture ends 62, which may consist of a tube ~~68~~ 62a having an inner lumen 70 through which ends 62 may be passed. Lumen 70 is dimensioned frictionally engage suture ends 62 so as to maintain adequate tension on suture S to create a hemostatic seal around catheter 64.

Please amend Page 17, line 20 through Page 18, line 3, as follows:

As may be seen in Figure 3A shaft 22 of cardioplegia catheter 20 must be shapable into a curve of very small radius in order to extend through both the aortic valve A V and mitral valve MV, a distal portion of the shaft which extends through the aortic valve being at an angle of around 100-170 degrees, preferably about 110 to 150 degrees, relative to the proximal portion of the shaft which extends through the mitral valve. Preferably, shaft 22 will be reinforced in at least the region of this curve with a wire winding (not shown) embedded in its outer wall to prevent the shaft from kinking. Suitable wire-wound shafts and methods of manufacturing such shafts are described in copending application Serial No. 08/664,716, filed June 17, 1996, , now issued as U.S. Patent No. 5,879,499, which is incorporated herein by reference.

Please amend Page 19, line 18 through Page 20, line 3, as follows:

Unlike the previous embodiment, cardioplegia catheter 80 further includes a ventricular balloon 110 spaced proximally from occlusion member 84 and first and second openings 90,94. The position of ventricular balloon 110 on shaft 82 is selected such that it will be disposed in the left ventricle adjacent the aortic valve when occlusion balloon 84 is in the ascending aorta between the brachiocephalic artery and the coronary arteries, usually being positioned about 4-8 cm proximally of occlusion balloon 84 for use in adult patients. Ventricular balloon 110 is inflated via a second inflation lumen 112 extending from a second inflation port 114 at the proximal end of the shaft to a second inflation opening 116 in shaft 82 within the ventricular balloon. The balloon will preferably be inflatable to a diameter of about 2-4 cm to facilitate occlusion of the ventricular outflow tract at the around the annulus of the aortic valve.

In the Claims:

1. A cardioplegia catheter for inducing cardioplegic arrest comprising:

a shaft with a distal end, a proximal end, an opening near the distal end, a port at the proximal end, and an inner lumen fluidly connecting the port and the opening, a distal portion of the shaft being configured to extend into the ascending aorta when ~~with~~ a proximal portion of the shaft extends ~~extending~~ into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof; and

an occlusion member mounted to the shaft distally of the opening and configured to occlude the ascending aorta between the brachiocephalic artery and the coronary ostia.

4. The cardioplegia catheter of claim 1 wherein the shaft is ~~at least~~ between about 25 cm and 75 cm in length.

19. A catheter system for inducing cardioplegic arrest comprising:

a cardioplegia catheter including:

a shaft with a distal end, a proximal end, an opening near the distal end, a port at the proximal end, and an inner lumen fluidly connecting the port and the opening, a distal portion of the shaft being configured to extend into the ascending aorta when ~~with~~ a proximal portion of the shaft extends ~~extending~~ into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof; and

a guiding device for guiding the distal portion of the shaft into the ascending aorta from the left chamber of the heart.

20. A catheter system for inducing cardioplegic arrest comprising:

a cardioplegia catheter including:

a shaft with a distal end, a proximal end, an opening at the distal end, a port at the proximal end, and an inner lumen fluidly connecting the port and the opening, a distal portion of the shaft being configured to extend into the ascending aorta when ~~with~~ a proximal portion

of the shaft extends ~~extending~~ into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof; and

an occlusion member mounted near the distal end of the shaft and configured to occlude the ascending aorta between the brachiocephalic artery and the coronary ostia;

a source of cardioplegic fluid in communication with the port at the proximal end of the shaft; and

an arterial return cannula ~~a blood flow device~~ positionable in an artery downstream of the occlusion member for maintaining circulation of oxygenated blood in the patient's arterial system.

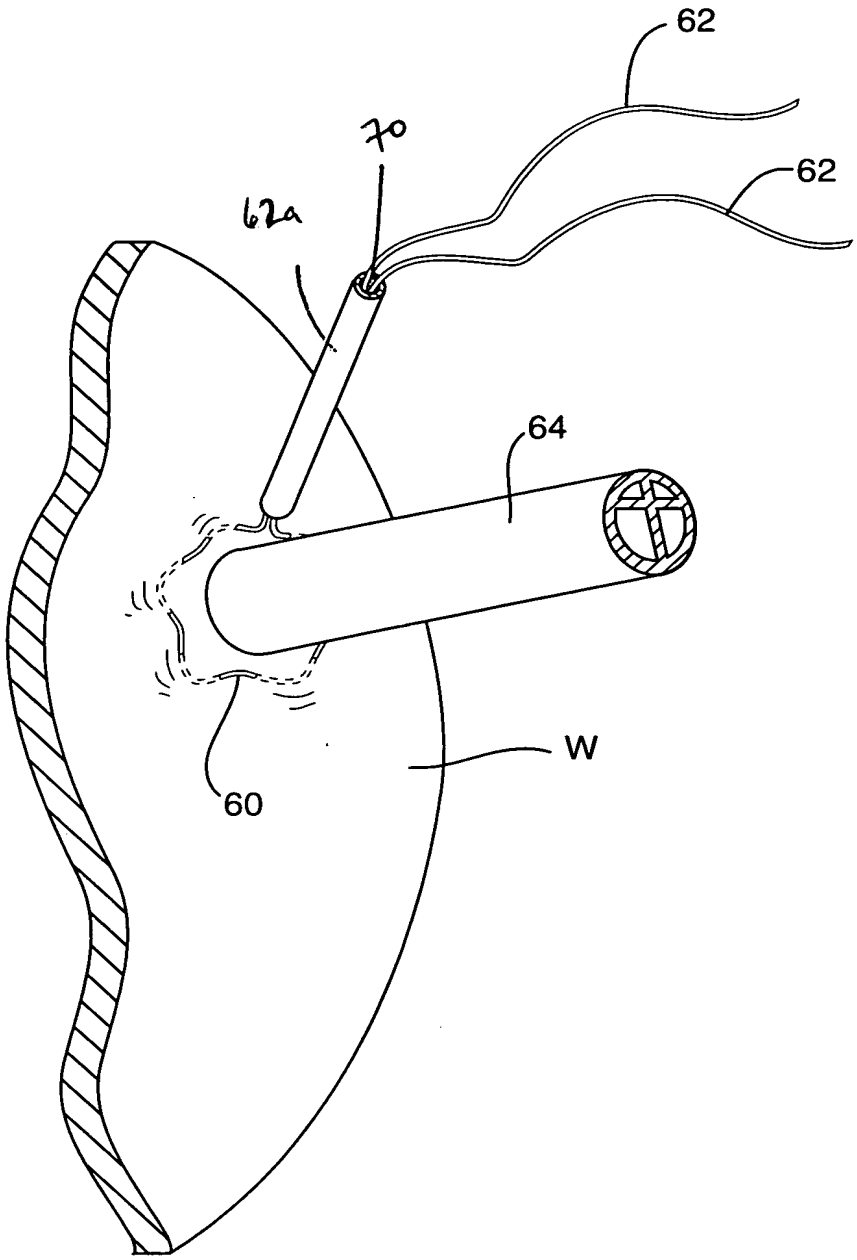

FIG. 4